

Applicant contacted the Office noting that the 3/20/09 outstanding Office action addressed claims 1-15 which had been canceled by the 10/20/04 amendments. The Office regrets any inconvenience caused to Applicant. A new Office action directed to pending claims 15-35 is below. The period for response will also be restarted as of the mailing of this new Office action

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-22,24-30,32-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Davis (USP 3,620,676).

Davis teach a disposable colorimetric indicating and sampling device(10) comprising a backing sheet(11) and a front member(12) that form a hollow tubular cavity(13) terminating in a bulb cavity(14). Column 1 lines 58+ teach the back sheet(11) and front sheet(12) are either heat sealed or adhesively joined. Reagent strip(16) is attached to the backing sheet(11).

The claimed “*indicator*”, “*reaction chamber*”, “*cup shaped element*” and “*covering film*” have been read on the taught “**reagent strip(16)**”, “**hollow tubular cavity(13)**”, “**bulb cavity(14)**” and “**front member(12)**” respectively.

Claims 16-30 and 32-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Naka et al. (USP 6,001,307).

Naka et al. teach in figure 1A a device comprising base member(5b) and cover(5a) that are integrated by an adhesive (column 10 line 9) to form a channel with an opening(4) and terminating in a suction generating chamber(1). Column 10 lines 37-47 teach the reagent can

coated or impregnated in the analytical section(3) of the device. Column 23 lines 48+ teach use of “wet reagents” in the analytical sections.

The claimed “*indicator*”, “*reaction chamber*”, “*cup shaped element*” and “*covering film*” have been read on the taught “**reagents**”, “**analytical section(3)**”, “**suction generating chamber(1)**” and “**cover(5a)**” respectively. The claimed “*indicator(11.0) is at least one liquid*” has been read on the taught “**wet reagents.**”

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis or Naka et al. in view of Shurben (USP 4,960,565).

See Davis and Naka et al. *supra*.

Davis and Naka et al. are silent to the claimed color comparison strip that borders the reaction chamber.

Shurben teaches a test device comprising bibulous pH test strips(16) adjacent to a color comparison reference standard. Shurben teach in column 5 lines 14-21 that it is advantageous to have a comparison reference standard adjacent to the test area to "... allowing a more precise comparison with the color scale .... and a clear and easy comparison to the color scale ...".

It would have been within the skill of the art to modify Davis or Naka et al. in view of Shurben and place a color comparison test strip adjacent to the reaction chamber to gain the above advantages.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis.

See Davis *supra*.

Davis is silent to the use of a liquid reagent.

Simple substitution of a known element for another to obtain predictable results is within the skill of the art. It is known in the art to use reagents in either a liquid or solid state depending upon the requirements of the assay. It is known in the art the same predictable results of analyte detection would have been expected if the reagent is in either a liquid or solid state. It would

have been within the skill of the art to modify Davis and use a liquid reagent as simple substitution of a known element for another to obtain the predictable results of analyte detection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards (USP 4,126,417) teaches color comparison areas adjacent to the reaction areas and is duplicative in teachings to Shurben.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1797

Application/Control Number: 10/511,827  
Art Unit: 1797

Page 6

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